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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/506,870	02/15/2000	Charles S. Vann	0550-0076.30	6464

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EXAMINER

BEX, PATRICIA K

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 10/09/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

72-17

Office Action Summary	Application No.		Applicant(s)	
	09/506,870		VANN ET AL.	
	Examiner		Art Unit	
	P. Kathryn Bex		1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 and 48-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 and 48-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>15</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 21-25, 51-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21, terms "large" and "small" are relative terms which render the claim indefinite. The terms "large" and "small" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear as to what Applicant considers "large" or "small" openings. Same deficiency was found in claims 22-23, 51, 55-57.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

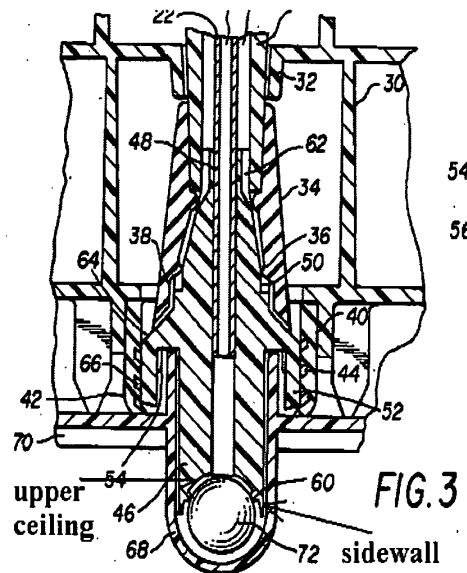
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3, 6-7, ~~14-17~~¹⁵ are rejected under 35 U.S.C. 102(b) as being anticipated by Eck (USP 4,685,480). *loops*

Eck teaches a combined washer and aspirator with a plurality of projections ~~48~~²⁸ depending from a support 30 at spaced-apart location defining a linear array and attached to a vacuum source via opening 14, effective to draw beads from containers 68. The projections having a

Art Unit: 1743

cavity formed at a lower end, each of the cavities defined by a lower opening, an upper ceiling region and a sidewall extending downwardly between the lower opening and upper ceiling region, wherein the upper ceiling region extends inwardly from the sidewall. Examiner has modified Figure 3 of Eck to clearly indicate the inwardly sloped upper ceiling region and downwardly extending sidewall (see Figure below).



Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459

(1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

Art Unit: 1743

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11-18, 16-18

7. Claims 2, 4-5, 8-9, 11-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eck (USP 4,685,480) in view of Ikeda *et al* (JP 64-80862) or Sakai *et al* (USP 4,937,048).

Eck as do not specifically recite the sidewall of each projection comprising a resiliently flexible material. Sakai *et al* teach an elastic cavity, i.e. carrier holding member 217, 124 formed at a lower end region of a suction nozzle 122, 218 each of the cavities defined by a lower opening and an upper ceiling region, and a sidewall extending between the lower opening and the upper ceiling region to hold the beads 127, 212 in the cavities and releasably retain them therein (Figs 11A, 13).

Since the arm is moved up and down with respect to the reaction vessel and the carrier is removed from the reaction tube by the carrier holding member arranged at the tip portion of the arm, it is possible to remove accurately the carrier contained in the reaction vessel even if the reaction vessel has a different shape (column 7, lines 39-45 of Sakai *et al*).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included in the bead dispensing system of Eck flexible cavity region, as taught by Sakai *et al*, in order to allow for greater contact between the lower end region of the projection supplying the suction source and the bead, thereby lowering the chance of dropping the bead prematurely. Moreover, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the sidewalls of the cavity from a flexible material, since it has been held to be within the general skill of a worker in the art to

Art Unit: 1743

select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

In regard to the specific diameter openings, both Eck and Sakai *et al* disclose the claimed invention except for the lower opening diameters and the longitudinal length of the sidewall. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the lower opening of the cavity from between 100-1,250 micrometers and the longitudinal length of the sidewall from about 0.5-1.25 times the diameter of the lower opening, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

8. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eck (USP 4,685,480) in view of Sakai *et al* (USP 4,937,048), as applied to claim 1 above, and further in view of Ekenberg *et al* (USP 5,272,510).

Eck and Sakai *et al* as discussed above, fail to teach a support which is held by a frame that is adapted to pivot about a vertical axis, rendering movable the projection array along a generally arcuate or circular pathway, and adapted for reciprocal linear motion along a generally vertical pathway, wherein such movement permits the projections to be aligned with the ampule array and lowered so that each projection can enter a respective one of the ampules. Ekenberg does teach a support 30 which is held by a frame 32 that is adapted to pivot about a vertical axis, rendering movable the projection array 28 along a generally arcuate or circular pathway, and adapted for reciprocal linear motion along a generally vertical pathway, wherein such movement permits the projections to be aligned with the ampule array 24 and lowered so that each

Art Unit: 1743

projection can enter a respective one of the ampules (cols. 8-9, Figs. 2, 7). The use of such a pivotal frame comprising the projections allows for the separation of the magnetic particles from the test media to be carried out simultaneously or sequentially, as desired (col. 8, lines 29-32).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included in the bead dispensing system of Eck and Sakai *et al* a pivotal frame, as taught by Ekenberg, in order to allow for the separation of the magnetic particles from the test media to be carried out simultaneously or sequentially, as desired.

9. Claims 19-20, 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eck (USP 4,685,480) in view of Sakai *et al* (USP 4,937,048), as applied to claim 1 above, and further in view of Hassler *et al* (WO 97/38318).

Eck and Sakai *et al* as discussed above, fail to teach a detection system having a field of view extending along each of the projection end regions and adapted to sense the presence or absence of a bead retained in the cavity. Hassler *et al* do teach system for counting beads 22 having a projection 15 with a lower end region, i.e. capillary, 2. Hassler *et al* disclose a detection system which includes a plurality of elongated light-conductive fibers 4, 6, each fiber having one end that extends along one of said projections and faces into said cavity, i.e. perpendicular to the longitudinal axis A of the capillary 2, and a second end disposed in optical communication via reflective surfaces 10, 11 with a camera 5 (pages 6-8, Figs. 1-2). As a result of the arrangement of the optical fibers parallel to the longitudinal axis A of the projection, the form of the device is very compact and space-saving. Moreover, such a robust construction provides that any movement or vibrations of the device will not impair the propagation of the measuring light along the optical light path (page 10, 2nd full paragraph).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included in the bead dispensing system of Eck and Sakai *et al* with the optical system, as taught by Hassler *et al*, in order to form a device that is very compact and space-saving.

10. Claims 21-25, 55, 57-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eck (USP 4,685,480) in view of Sakai *et al* (USP 4,937,048), as applied to claim 1 above, and further in view of Kambara *et al* (USP 6,288,220).

Eck and Sakai *et al* as discussed above, fail to teach a conduit assembly having a plurality of conduits for separately channeling a plurality of beads released from the cavities to desired locations on a substrate, the conduits having large openings at their upper ends disposed in an array having a center-to-center pitch like that of the projection array such the large openings are substantially alignable under the projections, and small openings at their lower ends in array having a center-to-center pitch like that of the substrate array. Kambara *et al* do teach a plurality of conduits 36 for separately channeling a plurality of beads released from the transfer device to desired locations on a substrate 34, the conduits having large openings at their upper ends disposed in an array having a center-to-center pitch like that of the projection array such the large openings are generally alignable thereunder, and small openings at their lower ends. Additionally, wherein the conduits slope inwardly along the longitudinal axis (Fig. 8A). Moreover, Kambara *et al* teach use of a laser cast on the plurality of conduits in direction parallel to the plate on which the conduits are arrayed and detecting the fluorescence emitted in each conduit with a two-dimensional detector, i.e. CCD (column 12, line 15- column 13, lines 41). The use of the conduits assures that the bead will fall into the proper test receptacle well and

Art Unit: 1743

thereby eliminates the problem of transfer and delivery of the units between the transfer device and the test receptacle tray when the tray has been miniaturized.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included in the bead dispensing system of Eck and Sakai *et al*, a plurality of conduits, as taught by Kambara *et al*, in order to assure that the bead will fall into the proper test receptacle well and thereby eliminates the problem of transfer and delivery of the units between the transfer device and the test receptacle tray when the tray has been miniaturized.

11. Claims 21-24, 51, 54, 57-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eck (USP 4,685,480) in view of Sakai *et al* (USP 4,937,048), as applied to claim 1 above, and further in view of Carre *et al* (EP 955 084 A1).

Eck and Sakai *et al* as discussed above, fail to teach a conduit assembly having a plurality of conduits for separately channeling a plurality of beads released from the cavities to desired locations on a substrate, the conduits having large openings at their upper ends disposed in an array having a center-to-center pitch like that of the projection array such the large openings are generally alignable thereunder, and small openings at their lower ends. Carre *et al* do teach a plurality of conduits 12 for separately channeling a plurality of beads (column 12, lines 15-54) released from the transfer device (column 11, lines 10-14) to desired locations on a substrate 66, the conduits having large openings at their upper ends disposed in an array having a center-to-center pitch like that of the projection array such the large openings are generally alignable thereunder, and small openings at their lower ends and wherein the conduits are curve along the longitudinal axis (abstract, Fig. 8). The use of the conduits allows for a very flexible transfer

Art Unit: 1743

system which can deliver beads from a multi-well plate having any number of wells to a plate having a large number of wells per area (column 21, line 48-58).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included in the bead dispensing system of Eck and Sakai *et al* a plurality of conduits, as taught by Carre *et al*, in order allow for the transfer of beads from a multi-well plate having any number of wells to a plate having a large number of wells per area (column 21, line 48-58).

12. Claims 21 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eck (USP 4,685,480) in view of Sakai *et al* (USP 4,937,048), as applied to claim 1 above, and further in view of Gilford *et al* (USP 4,236,825).

Eck and Sakai *et al* as discussed above, fail to teach the conduit assembly supported by a parallelogram linkage assembly for reciprocal arcuate movement between a raised position and a lowered position. However, Gilford *et al* do teach an elevator assembly 78 comprising a plurality of conduits 87 which is swingably supported on wall member 71 by rod elements 79 and 80 defining a parallelogram linkage whereby as the coupler block 42 engages and pushes against roller 73, the tube carrier arm 75 is arcuately swung while maintaining its horizontal position downwardly from its FIG. 7 position and in the "in direction" of the trackway 15 to its FIG. 8 position (column 5, line 58- column 6, line 9).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included in the bead dispensing system of Eck and Sakai *et al* a plurality of conduits supported by a parallelogram linkage assembly, as taught by Gilford *et al*,

Art Unit: 1743

in order provide automated and precise alignment of the individual conduits with each reaction well.

13. Claims 60-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eck (USP 4,685,480) in view of Sakai *et al* (USP 4,937,048), as applied to claim 1 above, and further in view of Gorlich *et al* (USP 5,447,736).

Eck and Sakai *et al* as discussed above, fail to teach a covering system comprising a continuous web of cover material mounted for movement from a supply position to a take-up position, a shearing blade mounted for reciprocal linear motion along a direction substantially normal to the web for cutting the cover material at a region between the supply position and the take-up position. Gorlich *et al* do teach a covering system comprising a continuous web of cover material mounted for movement from a supply position 30 to a take-up position 32, a shearing blade 35 mounted for reciprocal linear motion along a direction substantially normal to the web for cutting the cover material at a region between the supply position and the take-up position (col. 4, line 61- col. 5, line 9, Fig. 3). Such use of a covering means allows insures that the contents of the container will maintain an inert atmosphere until needed.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included in the bead dispensing system of Eck and Sakai *et al*, a covering mean, as taught by Gorlich, in order to assure the container will maintain an inert atmosphere until needed.

Allowable Subject Matter

14. Claims 53 and 56 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

15. The following is a statement of reasons for the indication of allowable subject matter: see previous office action.

Response to Arguments

16. Applicant's arguments with respect to claims 21-25, 51-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention have been considered but not considered persuasive. Examiner does not agree the use of the terms "large" and "small" when viewed in the light of its plain and ordinary meaning would clearly and distinctly convey to one of ordinary skill in the art the relationship of the related structure. Moreover, the specification fails to clarify the diameters of the "large" and "small" openings of the conduit assembly, therefore one of ordinary skill in the art determine from the language of the claim the metes and bounds of the scope of the invention. Applicant's arguments with respect to the previous rejection of claims 1-25, 48-62 under 35 U.S.C. 103(a) have been considered but are moot in view of the new ground(s) of rejection. See above Office Action.

Conclusion

17. No claims allowed.

Art Unit: 1743

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Bex whose telephone number is (703) 306-5697. The examiner can normally be reached on Mondays-Thursdays, alternate Fridays from 6:00 am to 3:30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 308-4037.

The fax number for the organization where this application or proceeding is assigned is (703) 872-9310 for official papers prior to mailing of a Final Office Action. For after-Final Office Actions use (703) 872-9311. For unofficial or draft papers use fax number (703) 305-7719. Please label all faxes as official or unofficial. The above fax numbers will allow the paper to be forwarded to the examiner in a timely manner.

Art Unit: 1743

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.

Kathryn Bex

P. Kathryn Bex

Patent Examiner

AU 1743

October 1, 2002

Jill Warden
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